

**GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

LOK SABHA
STARRED QUESTION NO. *52
TO BE ANSWERED ON 19th December, 2017

Price of Medical Devices

*52. SHRI RAMESH CHANDER KAUSHIK:
SHRI RAMDAS C. TADAS:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether the National Pharmaceutical Pricing Authority (NPPA) has carried out an assessment of mark-ups involved in the maximum retail prices of the following medical devices viz. Disposable Hypodermic Syringes, Disposable Hypodermic Needles, Disposable Perfusion Sets, In Vitro Diagnostic Devices for HIV, HBs Ag and HCV, Catheters, Intra Ocular Lenses, I V Cannulae, Bone Cements, Heart Valves, Scalp Vein Set, Orthopaedic implants, internal prosthetic replacements, Ligatures, Sutures and Staplers, Intra Uterine Devices, surgical dressings, umbilical tapes, blood and blood component bags and tubal rings; and

(b) if so, the details thereof along with the assessment/report/study of the NPPA which contains the mark-ups of the above mentioned medical devices?

ANSWER

**MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS AND
PARLIAMENTARY AFFAIRS (SHRI ANANTH KUMAR)**

(a) & (b): A statement is laid on the Table of the House.

Statement referred to in reply to Lok Sabha Starred Question No. *52 for answer on 19/12/2017 regarding Price of Medical Devices.

(a) & (b): Ministry of Health and Family Welfare has notified 23 medical devices as drugs under the Drugs and Cosmetics Act & Rules. Out of these, for 4 medical devices (Cardiac stents, drug eluting stents, condoms and intra uterine devices) which are in the National List of Essential Medicines (NLEM) and therefore covered under Schedule – I of Drugs (Prices Control) Order, 2013 (DPCO, 2013), the National Pharmaceutical Pricing Authority (NPPA) has fixed a price cap. The remaining 19 medical devices are non-scheduled formulations. The NPPA is mandated to monitor the Maximum Retail Price (MRP) of all these non-scheduled formulations including medical devices *viz.* Disposable Hypodermic Syringes, Disposable Hypodermic Needles, Disposable Perfusion Sets, In Vitro Diagnostic Devices for HIV, HBs Ag and HCV, Catheters, Intra Ocular Lenses, I V Cannulae, Bone Cements, Heart Valves, Scalp Vein Set, Orthopaedic implants, internal prosthetic replacements, Ligatures, Sutures and Staplers, Intra Uterine Devices, surgical dressings, umbilical tapes, blood and blood component bags and tubal rings. NPPA is also mandated to ensure that no manufacturer increases the maximum retail price of a drug more than ten percent of maximum retail price during preceding twelve months and where the increase is beyond ten percent of maximum retail price, it shall reduce the same to the level of ten percent of maximum retail price for next twelve months. In case of knee implants, it was found that there was a mark up upto 449%. The Government has fixed and notified the ceiling prices of orthopedic knee implants for knee replacement system in exercise of the powers under paragraph 19 of DPCO, 2013. NPPA also studies the mark ups involved in the maximum retail prices of these devices from time to time and their findings are uploaded in public domain at NPPA's website i.e. www.nppaindia.nic.in.
